

REMARKS

All rejections have been considered and are addressed in the amendment set forth above and the remarks which follow in order to overcome all objections and rejections and bring the application in condition for allowance at this stage of prosecution.

**1. Claims Rejection - 35 USC §112**

Claims 20, 35, 47 and 59-61 are rejected under 35 USC §112.

Claim 20 has been amended to recite that the flexible material has functional groups which are capable of reacting with antagonistic functions of at least one reactive compound, whereby said reaction imparts relative rigidity to said flexible material.

This limitation is supported by the specification, for instance on page 7, lines 17-31 and page 8, lines 11-13.

Claim 35 has been amended to recite that the reactive compound of claim 33 is a monofunctional agent selected in the group mentioned in claim 35.

Claim 47 has been amended to recite that the pre-form is made of polymeric or copolymeric material.

Claim 56 has been amended to recite a monofunctional or polyfunctional reactive compound, so that claims 59 and 61 find proper antecedent basis therein.

Claim 60 was cancelled in response to the Official Action dated May 9, 2002.

**2. Claim rejections - 35 USC §102**

Claims 19-21, 23,24, 27-33 stand rejected under 35 USC §102(b) as being anticipated by VANDERBILT 5,326,506.

The Examiner states that the method of forming the device, i.e. "*having a structural chemical modification*" is not germane to the issue of the patentability of the device itself.

We respectfully disagree because the structural modification is a positively recited structural feature of the intraocular lens which is not taught by VANDERBILT, or according to the Examiner's interpretation, a product-by-process feature which is also not taught in VANDERBILT.

According to amended claim 19, there is provided an intraocular lens which is comprised of a flexible material.

The intraocular lens has at least one relatively rigid portion, which is a chemical structural modification of the flexible material to impart relative rigidity.

Such a structure is therefore devoid of fusion or assembly zones used to join two distinct materials which have been contemplated or used in the past to produce bimaterial lenses.

This claim is not directed to a product by process as it relies on structural features, namely, the rigid portion being a chemical structural modification of the flexible material. In the instant application, the process leads to the obtention of a product which is structurally different from the products obtained by the prior art processes.

As previously explained, the rigid portion of the claimed lens is a chemical modification of the flexible material, while VANDERBILT discloses a process of interpenetrating two pre-existing polymeric networks, neither of which is structurally modified.

According to amended claim 20, a feature of this chemical structural modification is recited, namely, the functional groups borne by the flexible material, which are capable of reacting with antagonistic functions of at least

one reactive compound, whereby said reaction imparts relative rigidity to said flexible material.

VANDERBILT discloses a process of interpenetrating two pre-existing polymeric networks, whereby a physical assembly occurs between the rigid zone and the flexible zone.

As correctly stated by the Examiner, VANDERBILT teaches that *"a zone can be established to join the two parts of rigid material and flexible material"*.

VANDERBILT's process leads to the formation of a double block, where the central block is constituted of a rigid material and the two parts of the block are linked together through the interpenetration of the polymeric networks. The rigid material is not a chemical structural modification of the flexible material, as required by claim 19.

According to VANDERBILT, the zones of interpenetration contain both flexible material and rigid material, whereas in the claimed invention, there is no zone of interpenetration including both rigid material and flexible material, the chemically structurally modified zone is imparted with rigidity while the unmodified zone remains flexible.

However, according to the invention, even in the case where a mixture of monomers and/or a polymer blend is used to reinforce the structure of the material, this reinforcement is performed after a selective chemical structural modification of the flexible material has occurred.

Claims 19-23 and 26-32 are rejected under 35 USC §102(b) as being anticipated by BOS et al. 5,762,836.

BOS et al. are no more pertinent than the teachings of VANDERBILT. BOS et al. disclose a method of making an intraocular lens, where the optical part and the haptic part are mechanically bonded to each other during molding. The method is characterized by fitting together two solid parts. The attachment members previously formed of a rigid material (PMMA) are placed into a mold in which a mixture of monomers is poured, leading to a flexible material after polymerization.

As mentioned in the passage from column 4, line 66 to column 5, line 14, the bonding may be obtained either mechanically, by interpenetration or by adhesion.

BOS et al. therefore do not disclose a rigid material which is a chemical structural modification of the flexible material.

Claims 44-52, 54, 56-61 are rejected under 35 USC §102(e) as being anticipated by LOHMANN et al. 6,271,332.

LOHMANN et al. disclose a contact lens that comprise or consist essentially or entirely of a polymer which is obtainable by the thermal polymerization of a polysiloxane/polyol macromer with a polyisocyanate, such a macromer being made from an amino- or hydroxy-alkylated polysiloxane linked to at least one polyol component and, in some cases, via a bifunctional organic radical.

The Examiner states that "*Lohmann et al. disclose a method of making an intraocular lens by structurally modifying a flexible material, col. 15, lines 45-56*".

However, no reference to the structural modification of a flexible material can be found therein.

LOHMANN et al. merely indicate that "*The polymers according to the invention can be processed in a manner known per se to form moulded articles, especially to form contact lenses, for example by carrying out the step of crosslinking a macromer mentioned hereinbefore with a polyisocyanate or of crosslinking a prepolymer directly in a suitable contact lens mould.*"

Though crosslinking a macromer or a prepolymer can be understood as a way of hardening a polymer material, it cannot be derived therefrom that, before treatment, this polymer material was necessarily flexible.

Also, this treatment provides an overall hardening of the material which does not anticipate the selective rigidification of the flexible material according to the invention, where only a selected portion of the flexible material is imparted with rigidity.

The Examiner further refers to the passages in column 14, lines 65-67 to column 15, lines 1-2 to support the fact that LOHMANN et al. *"discloses the modification of the material can be done after the shaping of the pre-form into a IOL"* and column 16, lines 30-36 for further modification of the material *"outside the material with monomers"*.

Actually, LOHMANN et al. merely disclose that the prepolymer can be thermoplastically pressed and crosslinked to form a polymer and that *"moulded articles, especially contact lenses, can likewise be produced in that manner"*.

LOHMANN et al. further state in column 15, line 64 to column 16, line 2:

"Such contact lenses have a wide range of unusual and extremely advantageous properties. Among those properties, mention may be made, for example, of their excellent compatibility with the human cornea (if necessary after suitable surface treatment (coating)) and with lachrymal fluid, which is based on a balanced ratio of water content, oxygen permeability and mechanical and adsorptive properties."

and in column 16, lines 30-36:

"a molding may be coated with a layer of a hydrophilic polymeric material. Alternatively, hydrophilic groups may be grafted onto the surface of a molding, thereby producing a monolayer of hydrophilic material."

LOHMANN et al. thus clearly teach an overall and uniform treatment of the surface of a pre-formed device for imparting it with hydrophilic properties.

LOHMANN et al. are however silent as to selectively modifying a flexible portion of a polymeric material to impart it with rigidity.

With respect to claim 52, the Examiner acknowledges the fact that LOHMANN et al. do not disclose *"the step of shaping after the structural modification of the material"*.

It is clear from the above argumentation that such step cannot be taught or suggested by LOHMANN et al., because it would damage the treated surface of the lens, and therefore deprive this treatment from any industrial interest.



Finally, the Examiner's statement according to which *"applicant has not disclosed that the location of modification is for any purpose or solves any stated problem, or provides any advantage"* is respectfully contested.

It is clearly stated in the specification that the gist of the invention is to provide an intraocular implant which, through selective rigidification, comprises a flexible portion and a rigid portion, and where the rigid portion results from a structural chemical modification of the flexible portion.

LOHMANN et al. do not teach these characteristics, as LOHMANN et al. clearly provide an overall modification of the surface of a pre-formed material.

### **3. Claim Rejections - 35 USC §103**

The claim rejections over VANDERBILT, FREEMAN et al. 5,693,095, SCHERR et al. 3,391,224 and WANG et al. 6,011,082 have been dealt with in the response to the previous Official Actions.

Applicants reiterate and incorporate therein their position set forth in the response to the Official Action dated August 13, 2001 and May 9, 2002.

Claims 53, 55, 62, 63, 65 are rejected under 35 USC §103(a) as being unpatentable over LOHMANN et al. in view of VANDERBILT.

The Examiner acknowledges that LOHMANN et al. fail to disclose using a random (MMA-HMA) copolymer but points out that VANDERBILT teaches the use of MMA in a IOL and also that PMMA is used in the lens material.

As explained above, LOHMANN et al. do not suggest the selective structural modification of the claimed process, as it only relates to a uniform surface treatment of a pre-formed material.

Therefore, the combination of the teachings of VANDERBILT and LOHMANN et al. does not provide the claimed material.

In view of the present amendment and the foregoing remarks, it is believed that this application has been placed in condition for allowance.

In the event that there are any questions relating to this amendment, it would be appreciated if the Examiner would telephone the undersigned attorney.

Attached hereto is a marked-up version of the changes made to the claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

IN THE CLAIMS:

Claim 20 has been amended as follows:

--20. (twice amended) Intraocular lens according to claim 19, wherein [there are covalent bonds between the at least one relatively rigid portion and the unmodified flexible material] the flexible material has functional groups which are capable of reacting with antagonistic functions of at least one reactive compound, whereby said reaction imparts relative rigidity to said flexible material.--

Claim 35 has been amended as follows:

--35. (amended) Intraocular lens according to claim 33, wherein [the] said reactive compound is a monofunctional agent [is] selected in the group consisting of functional styrene, acrylic and methacrylic acids and their derivatives, allyl halides, carboxylic compounds and their derivatives, isocyanates, alkyl halides, epoxides, functional styrene derivatives, acryloyl methacryloyl halides, and allyl halides.--

Claim 47 has been amended as follows:

--47. (amended) A process according to claim 45, wherein the pre-form is made of polymeric or copolymeric

material, the step of selectively structurally modifying the flexible material [comprises] comprising polymerization after the chemical reaction of polymeric or copolymeric material.--

Claim 56 has been amended as follows:

--56. (amended) A process according to claim 44, wherein the step of selectively structurally modifying the flexible material comprises chemically reacting a monofunctional or polyfunctional reactive compound with a reactive element of the flexible material.--